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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/642,236	08/17/00	SCHWARTZ G	41145-1001

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1653	5

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/642,236	Applicant(s) SCHWARTZ, GEORGE R.
	Examiner Chih-Min Kam	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) 23-32 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-22, drawn to a method of treatment of neurologic damage using thrombopoietin, or thrombopoietin and thyroid hormone, or thrombopoietin and thyrotropin, classified in class 424, subclasses 85.1 and 198.1.

II. Claims 23-32, drawn to a pharmaceutical composition comprising thrombopoietin and thyroid hormone, or thrombopoietin and thyrotropin, classified in class 424, subclasses 85.1 and 198.1.

2. The inventions are distinct, each from the other because of the following reasons:

The product of Invention II and the method of Invention I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case thrombopoietin can be used to treat thromobocytopenia.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and because inventions I-II require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

During a telephone conversation with Stephen Slusher on March 22, 2001, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Informalities

The disclosure is objected to because of the following informalities:

The continuation data of this application are not completely listed in the Background of the Invention. Appropriate correction is required.

On page 7, lines 5-7 and 9-11, the reference (Mol Cell Neurosci 1997; (5/6); 420-32) by Ahlgren has been cited twice. Appropriate correction is required.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 09/499,198. Although the conflicting claims are not identical, they are not

patentably distinct from each other because both sets of claims treat neurological damage in a mammal (present application) and human (copending application). Note that mammal includes human and human is a mammal. Both sets of claims also administer thrombopoietin by oral, intravenous, intramuscular or intrathecal routes (claims 2-5). Moreover in the present application, claims 6-12 and 21 further comprise administering thyroid hormone and claims 13-17 and 22 further comprise administering thyrotropin with administering thrombopoietin, and claims 18-20 specify the source and the amount of thrombopoietin. Thus, claims 1-22 in each application are obvious variations of treating neurologic damage in human using thrombopoietin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for treating neurological damage in a mammal using thrombopoietin, or thrombopoietin and thyroid hormone, or thrombopoietin, thyroid hormone and thyrotropin because the specification only discloses cursory conclusions (page 1, lines 6-10, 15-18, 20-23; page 7, lines 17-26; page 9, line 6-14; page 9, line 16-20) and the claims recite no end point to the treatment, without data to support the findings, which state that thrombopoietin,

or thrombopoietin and thyroid hormone, or thrombopoietin, thyroid hormone and thyrotropin can be used to treat human neurological damage. However, there is no data regarding the administration of thrombopoietin resulting in the expression of PDGF (platelet-derived growth factor), thus causing the regeneration and repair of damaged neurons either *in vitro* or *in vivo* studies. The examples only indicate a delay on the symptoms of illness in the transgenic mouse model and the effects of thrombopoietin, thyroid hormone and thyrotropin are not clearly illustrated since there is no placebo group to compare with. Since it is not routine in the art to engage in *de novo* experimentation where the expectation of success is unpredictable, the skilled artisan would require additional guidance in order to make and use such agent. Without such guidance, the experimentation left to those skilled in the art is undue.

The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the nature of the invention, unpredictability in the art, the existence of working examples, the amount of direction or guidance presented, and the amount of experimentation necessary, especially, as here the data in Table 1 indicates recurrence of the disease state and subsequent death of the test animal two days post recurrence. See also Table 2 which presents indicative that the disease was fatal. Table 3 is also indicative of a protocol that still resulted in sickness. Thus, it is not clear that any treatment was successful. Note that here, the end points in 2/3 of the Examples are fatal.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because they lack essential steps as claimed in the process of treating neurologic damage. The omitted steps are: the site of administration and a step whereby the desired outcome (reducing or eliminating neurologic damage) and the time for the effective treatment using thrombopoietin, or thrombopoietin and thyroid hormone, or thrombopoietin, thyroid hormone and thyrotropin can be determined.

6. Claim 19 is indefinite because of the use of the terms "a fragment" and "a variant". The terms "a fragment" and "a variant" render the claim indefinite, it is not clear in the claim what kind of fragment and variant of thrombopoietin are as compared with human thrombopoietin, does the fragment or variant have the same function as the parent protein?

7. Claim 20 is indefinite, because neither the claim(s) nor the specification define the term "from about....about..." for the amount of thrombopoietin administered. The term "from about....about..." renders the claim indefinite, it is unclear what amount of thrombopoietin is administered.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

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March 29, 2001

Christopher S. F. Low

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